UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO ALL CLASS ACTIONS

DEFENDANT AVENTIS BEHRING L.L.C.'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR TRACK TWO CLASS CERTIFICATION

INTRODUCTION

Defendant Aventis Behring L.L.C. ("Behring"), now known as ZLB Behring L.L.C., joins the Track Two Defendants' Memorandum in Opposition to Class Certification.

Behring submits this individual memorandum in order to address issues particular to Behring that further preclude class certification.

To obtain class certification, plaintiffs "must establish that there is an individual class representative with standing to sue each defendant." *In re Pharm. Indus. AWP Litig.*, 230 F.R.D. 61, 80 (D. Mass. 2005). Plaintiffs have failed to demonstrate that any of their proposed class representatives can satisfy this burden as to Behring.

Specifically, plaintiffs' Motion for Class Certification establishes conclusively that no Class One or Class Two plaintiff purchased any Behring drug. Similarly, plaintiffs' Motion for Class Certification as to Class Three fails because plaintiffs seek certification of a Class Three subclass against Behring based on Pipefitters Local 537 Trust Funds' ("Pipefitters") alleged purchase of Immune Globulin, a multisource product manufactured by numerous

companies, including Behring. The mere possibility that Pipefitters may have purchased one Behring product cannot confer standing on Pipefitters to serve as a class representative against Behring, particularly since plaintiffs' own pleadings show that neither Pipefitters nor any other putative class representative purchased any drug manufactured by Behring. *See* Fourth Amended Master Consolidated Complaint ("FAMCC") at App. B., p. 6. Plaintiffs' Motion for Class Certification should be denied in its entirety as to Behring because plaintiffs have failed to proffer a class representative with standing as to Behring for any of the three proposed classes.

ARGUMENT

I. PLAINTIFFS HAVE NO STANDING TO OBTAIN CERTIFICATION OF A CLASS ONE SUBCLASS AS TO BEHRING

"It is well settled that prior to the certification of a class, and . . . before undertaking any formal typicality or commonality review, the district court must determine that at least one named class representative has Article III standing to raise each class subclaim." *In re Pharm. Indus. AWP Litig.*, 230 F.R.D. at 79 (*quoting Prado-Steiman v. Bush*, 221 F.3d 1266, 1279 (11th Cir. 2000)). Consistent with this principle, the Court declined to certify Class One as to Track 1 defendant Schering-Plough because the plaintiffs did not demonstrate that any proposed Class One representative made an AWP-based payment for a Schering-Plough subject drug. *See* Consolidated Order Re: Motion for Class Certification dated January 30, 2006. Here, plaintiffs have failed to allege, much less demonstrate, that any proposed Class One representative made *any* payment (much less an AWP-based payment) for Gammar, the only

Behring drug that plaintiffs have identified as a subject drug. As a result, the Court should decline to certify Class One as to Behring.

Specifically, the Estate of Young (and Mr. Young, as its representative) is the only class representative plaintiffs identify as to "Aventis" for Class 1. *See* Plaintiffs' Memorandum of Law in Support of Motion to Certify Claims with Respect to Track Two Defendants; May 8, 2006, [Proposed] Consolidated Order Re: Motion for Class Certification Order Track Two at ¶ 3. Plaintiffs propose the Estate of Young as a class representative based on the purchase of See Declaration of Donald E. Haviland, Jr. in Support of Plaintiffs' Motion to Certify Claims with Respect to Track 2 Defendants ("Haviland Decl.") at ¶ 13. However, it is indisputable that Behring never manufactured any form of this drug. *See* Declaration of Mary Ann Tomasso ("Tomasso Decl.") at ¶ 4 (filed electronically with this Court; see Docket Entry No. 2688).²

II. PLAINTIFFS HAVE NO STANDING TO OBTAIN CERTIFICATION OF A CLASS TWO SUBCLASS AS TO BEHRING

Similarly, no Class Two subclass can be certified as to Behring because plaintiffs have not alleged that any proposed Class Two representative made any payment (much less an AWP-based payment) for Gammar, the only Behring drug that plaintiffs have identified as a subject drug.

Appendix B to the FAMCC identifies Gammar-PIV, a pasteurized form of Gammar, as the only Behring product at issue. Appendix A to the FAMCC refers to Gammar-PIV and two related products manufactured by Behring, Gammar-IV and Gammar. The three products are referred to collectively herein as "Gammar."

Instead, plaintiffs do not even allege that Behring manufactured Instead, plaintiffs allege – completely incorrectly – that the administered to Young was manufactured by Behring's former parent company, Aventis Pharmaceuticals Inc. ("Aventis"). Haviland Decl. at ¶ 13. As noted, Behring has never manufactured any form of Tomasso Decl. at ¶ 4.

Plaintiffs have identified two instances when the proposed Class Two representative, Sheet Metal Workers National Health Fund, reimbursed for "Aventis" drugs: a single instance involving Anzemet®, and a single instance involving Taxotere®. It is indisputable that Behring never manufactured either of these drugs. Tomasso Decl. at ¶ 4. Indeed, plaintiffs do not allege that Behring manufactured either of these drugs. Instead, plaintiffs allege that they were manufactured by Behring's former parent company, Aventis. These transactions cannot confer standing as to Behring.³

III. A CLASS THREE SUBCLASS CANNOT BE CERTIFIED AS TO BEHRING

Plaintiffs' Motion to certify a Class Three subclass as to Behring should be denied for two independent reasons. First, Pipefitters, the only proposed Class Three representative, has failed to establish that it purchased any Behring product, and it therefore does not have standing to sue Behring. Second, any attempt to determine whether individual members of Class Three purchased Gammar, the only Behring product at issue, will require an extensive individualized inquiry.

Specifically, the single treatment involving Taxotere® occurred on March 3, 2005, outside the class period (January 1, 1995 to January 1, 2005) and almost a year after Behring ceased to have any corporate relationship to Aventis. Tomasso Decl. at ¶ 3. Behring was sold to CSL Limited effective March 31, 2004. *Id.* Behring became ZLB Behring L.L.C. at that time, and it has had no corporate relationship with Aventis since March 31, 2004. *Id.* Behring and Aventis certainly cannot be deemed part of a single "Aventis Group" (as alleged in paragraph 86 of the FAMCC) with respect to a period when the two companies had no corporate relationship. Equally fundamentally, during the period when Behring was a subsidiary of Aventis, Behring and Aventis manufactured and sold different drugs, placed their own sales, and made separate and independent pricing decisions. Tomasso Decl. at ¶ 2.

A. Pipefitters Lacks Standing To Sue or to Serve as a Class Representative Against Behring.

Pipefitters alleges that it purchased a single multi-source product, Immune Globulin, that was manufactured by Baxter, Bayer and Behring, as well as numerous entities that have not been named as defendants in this litigation. Example Ex. 1 to Declaration of Charles Hannaford ("Hannaford Dec."). This allegation establishes nothing more than that Pipefitters made payments for some drug which might have been Gammar, but might also have been another Immune Globulin product manufactured by another company. *Id.* This allegation is insufficient to establish Pipefitters' standing to sue Behring.

Indeed, Pipefitters has offered no evidence that it made any payment for Gammar, and Pipefitters' own pleadings suggest that it made no such payment. Specifically, Appendix B to the FAMCC – filed on March 10, 2006 – indicates that neither Pipefitters nor any other plaintiff purchased Gammar. *See* FAMCC App. B, p. 6. Moreover, because several companies manufacture other products that share the same J-Code as Behring's product, Pipefitters does not and cannot allege that Behring's product was the formulation administered to its member. Nor is such evidence likely to be uncovered. *See* Report of Steven J. Young. ⁵ Accordingly, Pipefitters'

Publicly available FDA records indicate that the following entities are currently licensed to manufacture Immune Globulin: BioPort Corporation; Massachusetts Public Health Biologic Laboratories; Talecris Biotherapeutics, Inc.; Baxter Healthcare Corporation; Grifols Biologicals Inc.; Instituto Grifols, S.A.; Octaharma Pharmazeutika Produktionsges.m.b.H.; ZLB Behring AG; ZLB Behring LLC; and ZLB Behring GmbH. See United States Food and Drug Administration, Center for Biologics Evaluation and Research, Current Licensed Establishments and Products, available at http://www.fda.gov/cber/ep/part3.htm (last visited June 11, 2006).

Even if plaintiffs could establish that Pipefitters purchased Gammar, they still cannot establish standing to sue Behring because the evidence is clear that Pipefitters did not rely on any allegedly fraudulent AWP. Instead, the testimony of Blue Cross Blue Shield of Massachusetts ("BCBSMA"), which administered the medical benefits claims of Pipefitters' members, establishes that AWP did not bear any relationship to the actual cost of any drug. *See* Killion Tr. at 137-139.

alleged overpayments for Immune Globulin are not traceable to any conduct of Behring, and Pipefitters lacks standing to sue Behring.

Nor does Pipefitters achieve standing to sue Behring by virtue of the fact that it seeks to represent a class of individuals and entities. *See Rivera v. Wyeth-Averst Laboratories*, 283 F.3d 315 (5th Cir. 2002); *In re Eaton Vance Corp. Secs. Litig.*, 220 F.R.D. 162, 169 (D. Mass. 2004) (cautioning against permitting a plaintiff to "sue a defendant against whom the plaintiff has no claim in a putative class action, on the theory that some member of the hypothetical class, if a class were certified, might have a claim."). As the Supreme Court has explained, "[s]tanding cannot be acquired through the backdoor of a class action." *Allee v. Medrano*, 416 U.S. 802, 828-29 (1974); *In re Pharm. Indus. AWP Litig.*, 230 F.R.D. at 193 (*quoting Allee*). Rather, in order to assert claims on behalf of Class Three, Pipefitters must first establish that it was personally injured by conduct traceable to Behring. *See Sierra Club v. Morton*, 405 U.S. 727, 734-35 (standing "requires that the party seeking review be himself among the injured."). Pipefitters has not established any such injury, and it therefore cannot seek relief on behalf of others allegedly injured by Behring.

In short, plaintiffs have not put forward a single named plaintiff with standing to sue Behring, despite having had ample opportunity to do so. This Court therefore need not consider whether the requirements of Rule 23 have been met as to Behring for Class Three.

Eaton, 220 F.R.D. at 169.

B. Individual Issues Predominate as to Immune Globulin, the Only Behring Product Which Pipefitters Might Have Purchased.

Finally, even if the plaintiffs could establish that Pipefitters has standing to sue Behring for purchases of Gammar, this Court still should not certify Class Three as to Behring because extensive individualized inquiry will be required to determine whether class members purchased Gammar or another entity's Immune Globulin product. Plaintiffs concede that at least three different manufacturers' versions of Immune Globulin share the same J-Code (Hannaford Dec. Ex. 1.), and they have produced no documents identifying the source of the Immune Globulin paid for by Pipefitters. The Court would be required to determine the source of the Immune Globulin at issue with respect to each individual Class Three member who alleges purchases of Immune Globulin, just as it must determine whether specific facts exist to establish the source of the Immune Globulin purchased by Pipefitters. The allegations as to Pipefitters illustrate the highly individualized and burdensome nature of making this determination for the Class Three plaintiffs. As a result, Class Three should not be certified as to Behring.

CONCLUSION

For the reasons set forth above, as well as those in the Joint Memorandum of Law in Support of the Track Two Defendants' Opposition to Plaintiffs' Motion for Class Certification, plaintiffs' Motion for Class Certification should be denied as to Behring.

AVENTIS BEHRING, LLC By its Attorneys,

Michael DeMarco (BBO #119960)
mdemarco@klng.com
Aimée E. Bierman (BBO #640385)
abierman@klng.com
KIRKPATRICK & LOCKHART
NICHOLSON GRAHAM LLP
State Street Financial Center
One Lincoln Street
Boston, MA 02111-2950
(617) 261-3100

William D. Nussbaum Jonathan T. Rees HOGAN & HARTSON L.L.P. 555 13th Street, NW Washington D.C. 20004 (202) 637-5600 FAX: (202) 637-5910

Dated: June 15, 2006

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2006 I served a true and correct copy of the foregoing on Plaintiffs' liason counsel, Thomas M. Sobol and Edward Notargiacomo, Hagens Berman Sobol Shapiro LLP, One Main Street, 4th Floor, Cambridge, MA 02142, by hand delivery.

Aimée E. Bierman